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PHILIP S. JOHNSON			KISH, JAMES M	
JOHNSON & JOHNSON				
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NEW BRUNSWICK, NJ 08933-7003			3737	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/598,590	REVIE ET AL.	
	Examiner	Art Unit	
	JAMES KISH	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) Claim(s) 45-85 is/are pending in the application.
 - 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) Claim(s) ____ is/are allowed.
- 7) Claim(s) 45-85 is/are rejected.
- 8) Claim(s) 68,70-72,78,79 and 85 is/are objected to.
- 9) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on 05 September 2006 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>9/5/06, 6/4/09, 6/4/09</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: ____ .

DETAILED ACTION***Information Disclosure Statement***

The information disclosure statement filed September 5, 2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because all references contained therein (except for F. Langiotz et al.) lack a date on the IDS. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

The disclosure is objected to because of the following informalities: The first sentence in the disclosure should state any and all priority associated with the application.

Appropriate correction is required.

Drawings

The drawings are objected to because the box(es) for, at least, numeral 104 and perhaps also 108, 110 and 112, should be labeled with a descriptive word. Box 104 is large enough for a descriptor to reside inside, while boxes 108,

110 and 112 may not require the same. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 68, 70-72, 78-79 and 85 are objected to because of the following informalities:

Claim 68 is objected to because it is unclear what it meant by "data items."

Claim 70 is objected to because "the first set of pelvic positions" should read "the first set of pelvic part positions."

Claim 71 is objected to because “the second set of pelvic positions” should read “the second set of pelvic part position.”

Claim 72 is objected to because “the first set of pelvic positions and the second set of pelvic positions” should include the word “part” in order to remain consistent.

With regard to claims 78 and 79, the “and/or” is being treated as stating “or.”

Claim 85 is objected to because “the geometric constraint that a two of the cardinal planes are perpendicular” would be better as stating, “that two of the...” Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 45, 77 and 82 are rejected under 35 USC 101 as being directed to non-statutory subject matter because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to another statutory class (such as a particular machine). *See Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). *See also In re Comiskey*, 499 F.3d 1365, 1376 (Fed. Cir. 2007) (request for rehearing *en banc* pending). The claims relate to determining cardinal planes (or planes parallel to the cardinal planes) of a subject’s pelvis. The independent method

claims do not comprise a sufficient tie to a particular machine. As an example of this lack of a tie to a particular machine, an artist may draw a picture using a pencil and paper (which constitutes an image – see claim 55) of a figure having a pelvis an on this drawing, the artist (or anyone) may define points associated with anatomical landmarks and use these positions to calculate cardinal (or otherwise parallel) planes. Specifically regarding claim 82, the “instrument” whose position is detected could be the pencil wherein the detection is the mark on the drawing where a person has contacted the paper with the pencil tip. Furthermore, there is no transformation of underlying subject matter to a different state or thing.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 45-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle, III (US Patent Pub. No. 2002/0077540) – herein referred to as Kienzle – in view of Sarin et al. (US Patent No. 6,711,431) – herein referred to as Sarin.

Kienzle discloses a computer assisted surgery system for assisting a surgeon in orthopaedic procedures. As described in the Abstract, "the surgeon is provided with information regarding the orientation of the cup with respect to a pelvic reference frame that is based on accepted pelvic landmarks. The positions of each landmark is calculated by the system when a probe with a virtual tip, separate from its physical tip, is overlaid on the landmark in roughly orthogonal images of the pelvis." In paragraph 46, Kienzle states that the "frontal" plane, the axial plane and a third, sagittal plane are defined (see Figure 9: third plane not shown). As can be seen in Figure 9, these planes a parallel to the cardinal planes of the pelvis and at least the landmarks 182 and 183 (note: there is a third landmark 184) are illustrated as being common to both planes 188 and 189. Kienzle does teach that "one or more landmarks or points" may be defined by the probe (see paragraph 44). However, Kienzle never states that more than three landmarks are used.

Sarin teaches non-imaging, computer assisted navigation systems for hip replacement surgery. In column 8, Sarin teaches that "in pelvic definition step

148, the physician uses an optically trackable manual probe 50 to palpate at least three, and preferably four, easily located anatomical landmarks on the pelvis (see lines 8-11).” It would have been obvious to one of ordinary skill in the art at the time the invention was made that using four points, as taught by Sarin, would better define the pelvic plane (see column 8, lines 26-28).

Regarding claim 46, it can be seen in Figure 9 that at least the landmarks 182 and 183 (note: there is a third landmark 184) are illustrated as being common to both planes 188 and 189.

Regarding claims 47-49, Kienzle states that the planes are the frontal, the sagittal and the axial (or transverse) planes.

Regarding claims 50 and 51, Kienzle teaches that “Alternatively, the virtual probe representation can be replaced with a straight line, a curved line, a plane, a curved surface, or some other graphic that allows for the alignment of the virtual probe with one or more landmarks or points (see paragraph 44).” Therefore, Kienzle does not limit its device to only three points and could provide any number of landmarks. Furthermore, Kienzle teaches, “Alternatively, other axes and planes may be defined without departing from the instant invention (see paragraph 46).”

Regarding claims 52 and 53, Kienzle states that the planes are the frontal, the sagittal and the axial (or transverse) planes.

Regarding claim 54, as stated by the Abstract, “The positions of each landmark is calculated by the system when a probe with a virtual tip, separate

from its physical tip, is overlaid on the landmark in roughly orthogonal images of the pelvis."

Regarding claim 55, Kienzle utilizes images of the pelvis, as exemplified at least by paragraph 47 as stating, "As the surgeon moves the positioning instrument (191), the display is updated in real time to show, graphically, the pose of instrument and implant representation (195) relative to the images of the pelvis."

Regarding claim 56, Sarin teaches a trackable marker attachable to the pelvis for tracking the position and orientation of the pelvis (see Figure 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a tracking marker as disclosed by Sarin in order to track in real-time the position of the pelvis in case the patient moves.

Regarding claim 57, Kienzle teaches applying a "virtual end" of a probe to respective anatomical features of the pelvis (see the Abstract).

Regarding claim 58, Kienzle teaches subcutaneously applying the "virtual end" of the instrument (see Figure 7).

Regarding claim 59, Kienzle teaches percutaneously applying the "virtual end" of the instrument (see Figure 7). Furthermore, Sarin teaches placing the physical end of its probe in percutaneous contact overlying an anatomical landmark (see column 8, lines 11-14).

Regarding claim 60, Sarin teaches that "the physician uses an optically trackable manual probe to palpate at least three, and preferably four, easily located anatomical landmarks on the pelvis.

Regarding claim 61, Kienzle teaches “a means for calculating a pelvic coordinate frame based on the at least three pelvic landmarks (see claim 9).” This includes calculating the third plane.

Regarding claim 62, Kienzle shows in Figure 9 that landmarks 182 and 183 are located at the spina iliaca anterior superior, while landmark 184 is located at the symphysis pubis (see paragraph 46).

Regarding claims 63, Kienzle teaches, “Alternatively, other axes and planes may be defined without departing from the instant invention (see paragraph 46).” It would be obvious to one of ordinary skill in the art to utilize any landmarks that are known to reside within the desired plane when defining that plane with the system registration steps taught by Kienzle - “a person of ordinary skill is also a person of ordinary creativity, not an automaton. (KSR International Co. v. Teleflex Inc. et al.).

Regarding claim 64, the symphysis pubis is common to at least two of the planes shown in Figure 9, thereby being interpreted as the first and second planes.

Regarding claim 65, both references teach an instrument for locating points of, or adjacent, the pelvis (see Figure 7 of Kienzle and Figure 3 of Sarin). As seen in these figures, both of these instruments contain tracking markers that are used by an associated tracking system to provide positional information with regard to the real tip location and/or a virtual tip location. Furthermore, Kienzle comprises computer that is used with its computer assisted surgery system,

comprising a data processing device and a memory for storing instructions that perform the method as taught at the previously with regard to claim 45.

Regarding claims 66 and 67, as seen in Figure 7 of Kienzle and Figure 3 of Sarin, both of these instruments contain tracking markers that are used by an associated tracking system to provide positional information with regard to the real tip location and/or a virtual tip location.

Regarding claim 68, Kienzle illustrates in Figure 7 that there are data items that represent the position of the instrument displayed on the screen of the system, as well as representing the virtual tip of the instrument.

Regarding claim 69, Kienzle teaches a computer assisted surgery system. The System comprises a tracking system and a computer system that work together to create the overall computer assisted surgery system. As such, they are integrated.

Regarding claim 70, Kienzle teaches that at least three pelvic points that are used to determine position of a coordinate frame including three planes. The first plane is determined by an axis which is determined by the left ASIS, right ASIS and a point at the pubic symphysis.

Regarding claim 71, Kienzle teaches that the second plane is determined by being perpendicular to the first axis (which incorporates the knowledge of two points) and a third point (the pubic symphysis).

Regarding claim 72, as described above with regard to claims 70 and 71, there is at least one common point.

Regarding claim 73, with regard to the rejection of claim 70 above, it is obvious that the first plane incorporates the landmarks taught by Kienzle.

Regarding claim 74, the rejection of claim 71 above makes it obvious that a line perpendicular to the first axis would require the knowledge of at least two points (since a line is two-dimensional) as well as a third point to define the plane. These points are common to both planes.

Regarding claim 75, Kienzle teaches that at least three pelvic points that are used to determine position of a coordinate frame including three planes. The first plane is determined by an axis which is determined by the left ASIS, right ASIS and a point at the pubic symphysis.

Regarding claims 76, Kienzle teaches, "Alternatively, other axes and planes may be defined without departing from the instant invention (see paragraph 46)." It would be obvious to one of ordinary skill in the art to utilize any landmarks that are known to reside within the desired plane when defining that plane with the system registration steps taught by Kienzle - "a person of ordinary skill is also a person of ordinary creativity, not an automaton. (KSR International Co. v. Teleflex Inc. et al.).

Regarding claim 77, the combination of the prior art was previously described with regard to claim 45 in such a manner that it reads similarly on the limitations of claim 77. See the main body of the rejection.

Regarding claim 78, the planes found in Figure 9 of Kienzle illustrate that the first and second planes are coincidental with first and second cardinal planes.

Regarding claim 79, Kienzle states that the planes are the frontal, the sagittal and the axial (or transverse) planes.

Regarding claims 80 and 81, Kienzle teaches that both planes utilize the point at the pubic symphysis.

Regarding claim 82, the combination of the prior art was previously described with regard to claim 45 in such a manner that it reads similarly on the limitations of claim 77. See the main body of the rejection.

Regarding claim 83, as seen in Figure 7 of Kienzle and Figure 3 of Sarin, both of these instruments contain tracking markers that are used by an associated tracking system to provide positional information with regard to the real tip location and/or a virtual tip location.

Regarding claim 84, Kienzle teaches that the left ASIS, the right ASIS and the pubic symphysis all lie within the first plane.

Regarding claim 85, in paragraph 46, Kienzle states "... a second axis (186) is perpendicular to the first axis and extends through the top of the pubic symphysis (184), and the third axis (187) is orthogonal to the first two axes (185 and 186)."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James Kish/
Primary Examiner, Art Unit 3737